

WHAT IS CLAIMED IS:

- 5 1. An apparatus for controlling the food flow through the stomach or esophagus of a patient, the apparatus comprising:
 an implanted adjustable restriction device engaging the patient's stomach or esophagus to form a restricted stoma opening in the stomach or esophagus,
10 an implanted adjustment device for adjusting said restriction device to change the size of the stoma opening,
 an implanted sensor for sensing at least one physical parameter associated with the patient, and
 a control device which controls said adjustment device to adjust said restriction device to change the size of the stoma opening in response to said sensor sensing a change in said physical parameter.
- 20 2. An apparatus according to claim 1, wherein said control device comprises an implanted internal control unit for directly controlling said adjustment device in response to signals from said sensor.
- 25 3. An apparatus according to claim 1, wherein said control device comprises an external control unit outside the patient's body for controlling said adjustment device in response to signals from said sensor.
4. An apparatus according to claim 3, wherein said external control unit directly controls said adjustment device in response to signals from said sensor.
- 30 5. An apparatus according to claim 3, wherein said external control unit stores information on said physical parameter sensed by said sensor and is manually operated to control said adjustment device based on said stored information.

6. An apparatus according to claim 1, wherein said control device comprises an implanted internal control unit and an external control unit outside the patient's body, for controlling said adjustment device in response to signals from said sensor.

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7. An apparatus according to claim 1, further comprising at least one implanted sender for sending information on said physical parameter sensed by said sensor.

8. An apparatus according to claim 1, wherein said sensor comprises a pressure sensor for sensing as said physical parameter the pressure in the patient's stomach or esophagus.

9. An apparatus according to claim 8, wherein said pressure sensor indirectly senses the pressure in the stomach or esophagus by sensing the pressure exerted by the stomach or esophagus against said restriction member.

10. An apparatus according to claim 8, wherein said control device controls said adjustment device to change the size of said stoma opening in response to said pressure sensor sensing a change in the pressure in the stomach or esophagus.

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11. An apparatus according to claim 10, wherein the apparatus is intended for restricting the food intake of an obese patient, and said control device controls said adjustment device to reduce said stoma opening in response to said pressure sensor sensing a pressure equal to or exceeding a predetermined value.

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12. An apparatus according to claim 10, wherein the apparatus is intended for restricting the food intake of an obese patient, and said control device controls said adjustment device to enlarge said stoma opening in response to said pressure sensor sensing a pressure below a predetermined value.

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13. An apparatus according to claim 10, wherein the apparatus is intended for restricting the food intake of an obese patient, and said control device controls said adjustment device to enlarge said stoma opening in response to said pressure sensor sensing a pressure equal to or exceeding a too high value.

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14. An apparatus according to claim 10, wherein the apparatus is intended for treating heartburn and reflux disease, and said control device controls said adjustment device to enlarge said stoma opening in response to said pressure sensor sensing a pressure equal to or exceeding a predetermined value.

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15. An apparatus according to claim 10, wherein the apparatus is intended for treating heartburn and reflux disease, and said control device controls said adjustment device to reduce or close said stoma opening in response to said pressure sensor sensing a pressure below a predetermined value.

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16. An apparatus according to claim 10, wherein the apparatus is intended for treating heartburn and reflux disease, and said control device controls said adjustment device to enlarge or fully open said stoma opening in response to said pressure sensor sensing a pressure equal to or exceeding a too high value, to avoid injurious high pressures in the stomach or esophagus.

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17. An apparatus according to claim 1, wherein said sensor comprises a position sensor for sensing as said physical parameter the orientation of the patient with respect to the horizontal.

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18. An apparatus according to claim 17, wherein the apparatus is intended for restricting the food intake of an obese patient, and said control device controls said adjustment device to increase said stoma opening in response to said position sensor sensing that the patient has assumed a substantially horizontal orientation.

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19. An apparatus according to claim 17, wherein the apparatus is intended for treating heartburn and reflux disease, and said control device controls said adjustment device to restrict or close said stoma opening in response to said position sensor sensing that the patient has assumed a substantially horizontal orientation.

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20. An apparatus according to claim 8, further comprising a position sensor for sensing the orientation of the patient with respect to the horizontal.

21. An apparatus according to claim 20, wherein the apparatus is intended for restricting the food intake of an obese patient, and said control device controls said adjustment device to increase said stoma opening in response to said position sensor sensing that the patient has assumed a substantially horizontal orientation.

22. An apparatus according to claim 20, wherein the apparatus is intended for treating heartburn and reflux disease, and said control device controls said adjustment device to restrict or close said stoma opening in response to said position sensor sensing that the patient has assumed a substantially horizontal orientation.

23. An apparatus according to claim 1, wherein said control device comprises a clock mechanism used for controlling said adjustment device to adjust said restriction member to keep said stoma opening at different sizes during different time periods of the day.

24. An apparatus according to claim 23, wherein said clock mechanism is used for controlling said adjustment device provided that said physical parameter sensed by said sensor does not override said clock mechanism.

25. An apparatus according to claim 1, wherein said control device comprises an implanted internal control unit and a wireless remote control which sets control parameters of said internal control unit from outside the patient.

26. An apparatus according to claim 25, wherein at least one of said control parameters, which is settable by said wireless control, is associated with said physical parameter.

5 27. An apparatus according to claim 25, wherein said internal control unit includes a clock mechanism used for controlling said adjustment device to adjust said restriction device to keep said stoma opening at different sizes during different time periods of the day.

10 28. An apparatus according to claim 27, wherein said wireless remote control is capable of setting said clock mechanism.

15 29. An apparatus according to claim 1, wherein said control device comprises a wireless remote control.

30 30. An apparatus according to claim 29, wherein said wireless remote control transmits a signal and is capable of transforming wireless energy from said signal into energy for powering implanted energy consuming components of the apparatus.

20 31. An apparatus according to claim 30, wherein said wireless remote control comprises a signal transmitter for transmitting said signal, an implanted signal receiver, and an implanted energizer unit for transforming wireless energy from said signal, as they are transmitted from said signal transmitter to said signal receiver, into said energy for powering implanted energy consuming components of the apparatus.

25 32. An apparatus according to claim 30, wherein the energy transformed from said wireless energy is used for energizing said implanted sensor.

30 33. An apparatus according to claim 1, wherein said adjustment device comprises an expandable cavity in said restriction device and the size of said stoma opening is reduced upon expansion of said cavity and increased upon contraction of

said cavity, and further comprising a reservoir for hydraulic fluid, said adjustment device distributing hydraulic fluid from said reservoir to expand said cavity and hydraulic fluid from said cavity to said reservoir to contract said cavity, to thereby change the size of said stoma opening.

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34. An apparatus according to claim 33, wherein said reservoir is attached to said restriction device.

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35. An apparatus according to claim 33, wherein said reservoir is fixed to said restriction device.

36. An apparatus according to claim 33, wherein said reservoir is integrated with said restriction device.

37. An apparatus according to claim 33, wherein said adjustment device comprises a pump for pumping fluid between said cavity and said reservoir.

38. An apparatus according to claim 37, wherein said pump is attached to said restriction device.

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39. An apparatus according to claim 37, wherein said pump is fixed to said restriction device.

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40. An apparatus according to claim 37, wherein said reservoir, pump and restriction device form a single piece.

41. An apparatus according to claim 37, wherein said reservoir, pump, sensor and restriction device form a single piece.

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42. An apparatus according to claim 37, wherein said pump is subcutaneously implanted in the patient remote from said restriction device.

43. An apparatus according to claim 1, wherein said adjustment device mechanically adjusts said restriction device.

5 44. An apparatus according to claim 1, further comprising an implanted battery for energizing said adjustment device.

10 45. An apparatus according to claim 1, further comprising an implanted accumulator for energizing said adjustment device.

15 46. An apparatus according to claim 45, wherein said accumulator comprises a capacitor.

20 47. An apparatus according to claim 1, further comprising an implanted battery for energizing said sensor.

25 48. An apparatus according to claims 1, further comprising an implanted accumulator for energizing said sensor.

30 49. An apparatus according to claim 48, wherein said accumulator comprises a capacitor.

50. An apparatus for controlling the food flow through the stomach or esophagus of a patient, the apparatus comprising:

an implanted adjustable restriction device engaging the patient's stomach or esophagus to form a restricted stoma opening in the stomach or esophagus,

an implanted adjustment device for adjusting said restriction device to change the size of said stoma opening, and

a control device which controls said adjustment device to adjust said restriction device to change the size of said stoma opening in response to the time of the day.

51. An apparatus according to claim 50, wherein said control device comprises a clock mechanism used for controlling said adjustment device to adjust said restriction device to keep said stoma opening at different sizes during different time periods of the day.

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52. An apparatus according to claim 50, wherein said control device comprises an implanted internal control unit and a wireless remote control which sets control parameters of said internal control unit from outside the patient.

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53. An apparatus according to claim 52, wherein said internal control unit includes a clock mechanism used for controlling said adjustment device to adjust said restriction device to keep said stoma opening at different sizes during different time periods of the day.

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54. An apparatus according to claim 53, wherein said wireless remote control is capable of setting said clock mechanism.

55. An apparatus according to claim 50, wherein said control device comprises a wireless remote control.

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56. An apparatus according to claim 55, wherein said wireless remote control transmits signals and is capable of transforming wireless energy from said signals into energy for powering implanted energy consuming components of the apparatus.

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57. An apparatus according to claim 56, wherein said wireless remote control comprises a signal transmitter for transmitting said signals, an implanted signal receiver, and an implanted energizer unit for transforming wireless energy from said signals, as they are transmitted from said signal transmitter to said signal receiver, into said energy for powering implanted energy consuming components of the apparatus.

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58. An apparatus according to claim 50, wherein said adjustment device comprises an expandable cavity in said restriction device and the size of said stoma opening is reduced upon expansion of said cavity and increased upon contraction of said cavity, and further comprising a reservoir for hydraulic fluid, said adjustment device
5 distributing hydraulic fluid from said reservoir to expand said cavity and hydraulic fluid from said cavity to said reservoir to contract said cavity, to thereby change the size of said stoma opening.

10 59. An apparatus according to claim 58, wherein said reservoir is attached to said restriction device.

60. An apparatus according to claim 58, wherein said reservoir is fixed to said restriction device.

15 61. An apparatus according to claim 58, wherein said reservoir is integrated with said restriction device.

62. An apparatus according to claim 58, wherein said adjustment device comprises a pump for pumping fluid between said cavity and said reservoir.
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63. An apparatus according to claim 62, wherein said pump is attached to said restriction device.

25 64. An apparatus according to claim 62, wherein said pump is fixed to said restriction device.

65. An apparatus according to claim 62, wherein said reservoir, pump and restriction device form a single piece.

30 66. An apparatus according to claim 62, wherein said pump is subcutaneously implanted in the patient remote from said restriction device.

67. An apparatus according to claim 50, wherein said adjustment device mechanically adjusts said restriction device.

68. An apparatus according to claim 50, further comprising an implanted
5 battery for energizing said adjustment device.

69. An apparatus according to claim 50, further comprising an implanted
10 accumulator for energizing said adjustment device.

70. An apparatus according to claim 69, wherein said accumulator comprises
a capacitor.

71. A method of controlling the food flow through the stomach or esophagus
of a patient comprising:

15 (a) surgically implanting in the patient an adjustable restriction device
engaging the patient's stomach or esophagus to form a stoma opening in the
stomach or esophagus;

20 (b) surgically implanting in the patient an adjustment device which adjusts the
restriction device and a sensor for sensing at least one physical parameter
associated with the patient; and

(c) controlling the adjustment device to adjust the restriction device to change
the size of the stoma opening in response to the sensor sensing a change in the
physical parameter.

25 72. A method as recited in claim 71, wherein (a) and (b) is practiced on a
patient suffering from morbid obesity, and the sensor comprises a pressure sensor
for directly or indirectly sensing as the physical parameter the pressure in the
stomach or esophagus.

30 73. A method as recited in claim 72, wherein (c) is practiced to reduce the
stoma opening when the pressure is at a pressure value commonly occurring when
the patient eats and to enlarge the stoma opening when the pressure is at a pressure
value commonly occurring between meals.

74. A method as recited in claim 72, wherein (c) is practiced to substantially fully open the stoma opening when the pressure is at a pressure value commonly occurring when the patient is sleeping at night.

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75. A method as recited in claim 72, further comprising (d) controlling the adjustment device in response to the time of the day to vary the stoma opening.

76. A method as recited in claim 75, wherein (d) is practiced unless overridden
10 by the pressure sensor①

77. A method as recited in claim 72, wherein (c) is practiced to substantially fully open the stoma opening when the pressure sensor senses an exceedingly high pressure, to avoid that injurious pressures arise in the stomach or esophagus.

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78. A method as recited in claim 71, wherein (a) and (b) is practiced on a patient suffering from morbid obesity and the adjustment device is implanted in the patient's torso, and the sensor comprises a position sensor for sensing as the physical parameter the orientation of the patient's torso with respect to the horizontal.

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79. A method as recited in claim 78, wherein (c) is practiced to enlarge the stoma opening when the position sensor senses a substantially horizontal orientation of the patient's torso.

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80. A method as recited in claim 78, further comprising (d) controlling the adjustment device in response to the time of the day to vary the stoma opening.

81. A method as recited in claim 80, wherein (d) is practiced unless overridden by the position sensor.

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82. A method as recited in claim 71, wherein (a) and (b) is practiced on a patient suffering from heartburn and reflux disease, and the sensor comprises a

pressure sensor for directly or indirectly sensing as the physical parameter the pressure in the stomach or esophagus,

83. A method as recited in claim 82, wherein (c) is practiced to enlarge the
5 stoma opening when the pressure is at a pressure value commonly occurring when
the patient eats and to reduce or close the stoma opening when the pressure is at a
pressure value commonly occurring between meals.

84. A method as recited in claim 82, wherein (c) is practiced to restrict or close
10 the stoma opening when the pressure is at a pressure value commonly occurring
when the patient is sleeping at night.

85. A method as recited in claim 82, further comprising (d) controlling the
15 adjustment device in response to the time of the day to vary the stoma opening.

86. A method as recited in claim 85, wherein (d) is practiced unless overridden
by the pressure sensor.

87. A method as recited in claim 82, wherein (c) is practiced to substantially
20 fully open the stoma opening when the pressure sensor senses an exceedingly high
pressure, to avoid that injurious pressures arise in the stomach or esophagus.

88. A method as recited in claim 71, wherein (a) and (b) is practiced on a
patient suffering from heartburn and reflux disease and the adjustment device is
25 implanted in the patient's torso, and the sensor comprises a position sensor for
sensing as the physical parameter the orientation of the patient's torso with respect
to the horizontal.

89. A method as recited in claim 88, wherein (c) is practiced to restrict or close
30 the stoma opening when the position sensor senses a substantially horizontal
orientation of the patient's torso.

90. A method as recited in claim 89, further comprising (d) controlling the adjustment device in response to the time of the day to vary the stoma opening unless overridden by the position sensor.

5 91. A method of controlling the food flow through the stomach or esophagus of a patient comprising:

(a) surgically implanting in the patient an adjustable restriction device engaging the patient's stomach or esophagus to form a stoma opening in the stomach or esophagus;

10 (b) surgically implanting in the patient an adjustment device which adjusts the restriction device; and

(c) controlling the adjustment device to adjust the restriction device to change the size of the stoma opening in response to the time of the day.

15 92. A method as recited in claim 91, wherein (c) is practiced to keep the stoma opening at different sizes during different time periods of the day.

20 93. A method of improving the quality of life of an obese patient having an adjustable restriction device engaging the patient's stomach or esophagus to form a stoma opening in the stomach or esophagus, the method comprising:

(a) surgically implanting an adjustment device which adjusts the restriction device and a sensor in the patient operatively associated with the stoma opening;

(b) sensing at least one physical parameter of the patient using the sensor; and

25 (c) controlling the adjustment device to enlarge the stoma opening in response to the sensor sensing a significant change in the physical parameter.

30 94. A method as recited in claim 93, wherein (b) is practiced by sensing the pressure in the patient's stomach, and (c) is practiced so that if the pressure in the patient's stomach is below a predetermined value then the adjustment device is controlled to enlarge the stoma opening.

95. A method as recited in claim 93, wherein (b) is practiced by sensing the pressure in the patient's stomach, and (c) is practiced so that if the pressure in the patient's stomach is above a predetermined value then the adjustment device is controlled to reduce the stoma opening.

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96. A method as recited in claim 93, wherein (b) is practiced by sensing the orientation of the patient with respect to the vertical, and (c) is practiced so that if the patient is substantially horizontal then the adjustment device is controlled to enlarge the stoma opening.

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97. A method as recited in claim 94, wherein (b) and (c) are practiced to substantially fully open the stoma opening when the pressure in the stomach is at a pressure value commonly occurring when the patient is sleeping at night.

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98. A method as recited in claim 93, further comprising implanting a control unit in the patient, and operating the control unit exteriorly of the patient in a non-invasive manner to control the adjustment device.

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99. A method of controlling the food flow through the stomach or esophagus of a patient comprising:

in a laparoscopic surgery procedure insufflating the abdomen of the patient to form a pneumoperitoneum;

introducing at least one laparoscopic trocar into the abdomen;

introducing an adjustable restriction device, an adjustment device for adjusting

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the restriction device and a sensor for sensing at least one physical parameter associated with the patient into the abdomen;

placing the adjustment device, sensor and adjustable restriction device in the patient's abdomen, so that the restriction device engages the patient's stomach or esophagus to form a stoma opening in the stomach or esophagus; and

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controlling the adjustment device to adjust the restriction device to change the size of the stoma opening in response to the sensor sensing a change in the physical parameter.